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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,212	06/23/2000	Ursula Buchholz	15280-398100US	9937

7590 06/13/2002

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EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/13/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,212

Applicant(s)

BUCHHOLZ ET AL.

Examiner

Stacy S Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 30-45, 48-56, 83, 84, 88, 89, 93, 94, 96, 97, 100 and 101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29, 46, 47, 57-82, 85-87, 90-92, 95, 98 and 99 is/are rejected.
- 7) ☒ Claim(s) 14, 24, 61, 72, 98 and 99 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-29, 46-47, 57-82, 85-87, 90-92, 95, 98-99, and RSV Subgroup A and B, F, G, SH and M2 proteins is acknowledged. Claims 30-45, 48-56, 83, 84, 88, 89, 93, 94, 96, 97, 100, 101 and non-elected groups in claims 98-99 are withdrawn from consideration.

Specification

2. The abstract of the disclosure is objected to because it is more than 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claims 14, 24, 61, 72, 98 and 99 are objected to because of the following informalities:
- Claims 14, 24, 61 and 72 lack proper punctuation.
 - Claims 98 and 99 recite non-elected inventions.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46, 47 and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 46 recites that the virus of claim 1 is a virus. This claim is redundant.

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- Claim 47 recites that the virus of claim 1 is a subviral particle. It is unclear how the virus of claim 1 can be a subviral particle.
- Claim 87 lacks antecedent basis for "the isolated polynucleotide" in claim 59.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

a) Claims 1-2, 6-8, 16, 46, 63-66, 73, 82 and 90 are rejected under 35 U.S.C. 102(a) as being anticipated by Buchholz *et al* (Virology, 1999). The claims are drawn to an isolated infectious chimeric RSV comprising N, P, L, polymerase elongation factor, RSV background genome or antigenome, combined with a heterologous gene from a different RSV to form a human-bovine chimeric RSV genome or antigenome. The heterologous gene can be RSV N, P,

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M2, L, F, G, leader, trailer or intergenic region. The gene can be a counterpart of the background genome and correspond to the wild-type gene order position. Also claimed are nucleic acids encoding the chimeric virus described above. The human RSV can be from subgroups A or B.

Buchholz teaches recovery and construction of nucleic acids that encode infectious chimeric RSV comprising N, P, L, polymerase elongation factor, RSV background genome or antigenome, combined with a leader sequence from a human RSV (subgroup A) to form a human-bovine chimeric RSV genome or antigenome (abstract, page 252, col. 2, line 3, and pages 254-255, bridging paragraph). Therefore, Buchholz anticipates claims 1-2, 6-8, 16, 46, 63-66, 73, 82 and 90.

b) Claims 1-29, 46-47, 57-82, 85-87, 90-92, 95, 98 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy *et al* (WO 98/02530). The claims are drawn to an isolated, infectious, chimeric human-bovine RSV, having protein substitutions from human RSV (subgroup A or B) and bovine RSV. Also claimed are immunogenic compositions and polynucleotides encoding the chimeric RSVs.

Murphy teaches that infectious RSV for use in humans as vaccines can be modified to be attenuated by replacing HRSV epitopes or proteins with BRSV counterparts (page 7, lines 10-37). Other alterations can be made such as changing the order of genes (page 10, lines 9-24). Proteins from PIV such as HN or F can be incorporated into the chimeric RSV (claim 23). Collins teaches that individual internal genes of HRSV can be replaced with BRSV NS1, NS2, N, P, M, SH, M2-1, M2-2 L, F or G proteins from subgroups A or B (page 10, lines 24-38, page

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11, lines 1-20). Collins' chimeric can be RSV or a subviral particle (page 12, lines 28-30).

Therefore, Collins anticipates the claims.

c) Claims 1-29, 46-47, 57-82, 85-87, 90-92, 98 and 99 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins (6,364,957). The claims are drawn to an isolated, infectious, chimeric human-bovine RSV, having protein substitutions from human RSV (subgroup A or B) and bovine RSV. Also claimed are immunogenic compositions and polynucleotides encoding the chimeric RSVs.

Collins teaches that infectious RSV for use in humans as vaccines can be modified to be attenuated by replacing HRSV epitopes or proteins with BRSV counterparts (col. 7, lines 49-59). Other alterations can be made such as changing the order of genes (col. 7, lines 29-33) or mutations in cis-acting signals (col. 10, lines 49-51). Collins teaches that individual internal genes of HRSV can be replaced with BRSV NS1, NS2, N, P, M, SH, M2-1, M2-2 L, F or G proteins from subgroups A or B (col. 10, lines 20-31, col. 11, lines 17-20). Collins' chimeric can be RSV or a subviral particle (col. 5, lines 61-62). Therefore, Collins anticipates the claims.

Conclusion

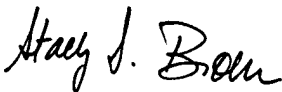
6. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive

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transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
June 12, 2002



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER